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ORIGINAL ARTICLE

Five-year prospective clinical study of posterior three-unit zirconia-based fixed dental prostheses

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Abstract This prospective clinical trial aimed at evaluating the clinical performance of three-unit posterior zirconia fixed dental prostheses (FDPs) after 5 years of clinical function. Thirty-seven patients received 48 three-unit zirconia-based FDPs. The restorations replaced either a premolar or a molar. Specific inclusion criteria were needed. Tooth preparation was standardized. Computer-aided design/computer-assisted manufacturing frameworks with a 9-mm^2 cross section of the connector and a 0.6-mm minimum thickness of the retainer were made. The restorations were luted with resin cement. The patients were recalled after 1, 6, 12, 24, 36, 48, and 60 months. The survival and success of the ceramics and zirconia were evaluated. The technical and aesthetic outcomes were examined using the United States Public Health Service criteria. The biologic outcomes were analyzed at abutment and contralateral teeth. Descriptive statistics were performed. All FDPs completed the study, resulting in 100% cumulative survival rate and 91.9% and 95.4% cumulative success rates for patients wearing one and two FDPs, respectively. No losses of retention were recorded. Forty-two restorations were rated alpha in all measured parameters. A minor chipping of the ceramics was detected in three restorations. No significant differences between the periodontal parameters of the test and control teeth were observed. Five-year clinical results proved that three-unit posterior zirconia-based FDPs were successful in the medium term for both function and aesthetic. Zirconia can be considered a promising substitute of metal frameworks for the fabrication of short-span posterior prostheses.

Keywords Zirconia · All ceramic · Prosthodontics · Fixed dental prostheses (FDPs)

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Introduction

To date, polycrystalline high-strength ceramics are being increasingly used as core materials for crowns and fixed dental prostheses (FDPs) due to the noticeable aesthetic demand of the patients, also in the presence of higher occlusal loads than those borne by the conventional ceramics of the past [1–4]. Due to the introduction of these high-strength ceramic materials and of advanced computer-aided design/computer-assisted manufacturing (CAD–CAM) systems, all-ceramic three-unit FDPs have become a viable treatment option [3, 4].

In particular, partially stabilized zirconia is characterized by higher mechanical properties than those showed by all of the other dental ceramics [4–7], like the flexural strength (900–1,200 MPa) and the fracture toughness (9–10 MPa $m^{1/2}$) mainly due to the well-studied phenomenon of "transformation toughening." Moreover, from the

clinical point of view, this material has been demonstrated to be highly biocompatible, not to enhance bacterial adhesion and to require well-known restorative procedures, like the conventional cementation [8–13].

Several studies proved that zirconia shows adequate properties in order to guarantee clinical serviceability when used in the frameworks of posterior FDPs and may be considered as a possible alternative to metal castings [2, 4–7, 14].

Although a few studies reported noticeable fracture rates of the veneering porcelain [15–20], the clinical performances of zirconia FDP frameworks are very promising, particularly the three-unit bridges [4, 21–31]. Sailer et al. [4] reported about 25% minor and 8% major chippings, resulting in a total chipping rate of about 33% for zirconia FDPs. The use of such frameworks for more extended FDPs is still under current evaluation: although very good in vitro results were obtained in terms of mechanical resistance to fracture, further in vivo investigations will be necessary to confirm a long-term clinical success of zirconia four- to five-unit bridges [32].

The primary aim of the present prospective clinical study was to evaluate the clinical efficacy regarding fracture resistance of tooth-supported posterior three-unit zirconia FDPs after 5 years of clinical service. The secondary aim was to assess biologic and technical complications over time during function.

Materials and methods

Thirty-seven patients (16 males, 21 females) in need of at least one FDP in the posterior region of the maxilla or mandible were recruited for the study. The patients' age ranged between 21 and 68 years with a mean age of 45.3 ±11.6 years. All patients were recruited at the Department of Prosthodontics of the University "Federico II" of Naples (Italy) from November 2004 to April 2005 (baseline). The requirements of the Helsinki declaration were fulfilled, the patients provided written informed consent, and the study was approved by the ethical committee of the University. The following inclusion criteria were used to recruit patients:

- Good general health;
- ASA I or ASA II according to the American Society of Anesthesiologists;
- Periodontal health;
- Angle class I occlusal relationship;
- Minimum 20 teeth;
- Good oral hygiene;
- No evident signs of occlusal parafunctions and/or temporomandibular disorders.

Furthermore, the abutment teeth had to fulfill the following inclusion criteria:

- Periodontal health (absence of tooth mobility, absence of furcation involvement);
- Proper positioning in the dental arch (tooth axes adequate for an FDP);
- Sufficient occlusocervical height of the clinical crown (≥4 mm) for the retention of an FDP;
- Vital or endodontically treated to a clinically sound state;
- Opposing natural teeth or fixed prostheses.

In the presence of the following conditions, patients were excluded from the study:

- Subjects preferring implant-supported prostheses;
- High caries activity;
- Occlusal–gingival height of the abutment teeth <4 mm;
- Reduced interocclusal distance or supraerupted opposing teeth;
- Unfavorable crown-to-root ratio;
- Severe wear facets, clenching, bruxism;
- Presence of removable partial dentures;
- Pregnancy or lactation.

A total of 48 three-unit zirconia FDPs was fabricated; 11 patients received two FDPs each. The pontic element had to replace either a first or second premolar or a first molar. Twenty-four FDPs were placed in the maxilla in order to replace 12 premolars and 12 molars, and the other 24 FDPs were placed in the mandible replacing nine premolars and 15 molars. One of the maxillary prostheses was designed with a mesial cantilever (first premolar). The locations of the FDPs are shown in Table 1.

Table 1 Location of the fixed dental prostheses

Site	Abutments	Number	Cantilevers
Maxilla	13–14–15	2	–
	14–15–16	2	–
	15–16–17	6	–
	23–24–25	4	–
	24–25–26	4	1 (24)
	25–26–27	6	–
Mandible	33–34–35	1	–
	34–35–36	2	–
	35–36–37	7	–
	43–44–45	1	–
	44–45–46	5	–
	45–46–47	8	–

Prosthodontic procedures

All of the clinical procedures were performed by four experienced calibrated prosthodontists. Oral hygiene, core buildups, endodontic therapies, and post-and-core placement were carried out before the prosthodontic procedures. Alginate impressions were taken to get study gypsum casts, for making diagnostic wax-up, self-polymerizing resin (Elite SC Tray, Zhermack, Badia Polesine, Italy) customized impression trays, and acrylic temporary restorations. Silicon indexes were obtained from the diagnostic wax-up in order to check a proper tooth structure reduction during the procedures of abutment preparation that were performed and standardized as follows, according to the requirements of the CAD–CAM framework production:

- Margin design: 1-mm circumferential rounded chamfer, with a particular care paid to getting rounded line cavosurface angles to prevent stress concentrations;
- Axial reduction: 1.5 mm;
- Occlusal reduction: 1.5–2 mm;
- Total occlusal convergence angle: 10–14°.

The margins of the preparation were slightly subgingival, never violating the biologic width. The acrylic resin temporary restorations were intraorally relined with self-polymerizing resin (Jet Kit, Lang, Wheeling, IL, USA) and then cemented with a eugenol-free luting agent (TempBond NE, Kerr Corporation, Orange, CA, USA); a careful occlusal adjustment of the provisional restorations was performed when needed. At least 10 to 14 days of waiting was done after tooth preparation before taking the final impression in order to allow soft tissues to recover from the preparation trauma. The impression procedure was performed by positioning two nonimpregnated retraction cords (Ultrapak, Ultradent, South Jordan, UT, USA) and taking full-arch impressions by customized autopolymerizing acrylic impression trays and polyether materials (Impregum and Permadyne-L, 3M ESPE, Seefeld, Germany). Interocclusal records were registered by means of a self-polymerizing A-silicone (Occlufast, Zhermack). Then, the provisional restorations were cemented again as previously described.

Master casts were made of super hard gypsum (Elite Rock, Zhermack), mounted in a semi-adjustable articulator (Whip Mix 8500, Whip Mix Co., Louisville, KY, USA). A die spacer (<30-μm thick) was applied at the occlusal and axial surfaces of the abutment, starting 1 mm above the preparation margin. Master casts were mechanically captured and digitized by means of the Procera CAD–CAM System (Procera Forte, Nobel Biocare AB, Goteborg, Sweden). Zirconia frameworks were designed providing space for an even thickness of the veneering ceramic. Scanned data were enlarged by 20–25% to compensate for sintering shrinkage. The frameworks were milled from presintered zirconia blanks at the Procera center (Nobel Biocare) and finally sintered to full density. Missing premolars were restored with an ovate pontic design, whereas missing molars were restored with a modified ridge lap-type pontic design.

As recommended by the manufacturer, the minimum connector surface area was 9 mm^2 and the minimum retainer thickness was 0.6 mm. The framework thickness was measured at defined points using a digital caliper with an accuracy of 0.01 mm.

Then, the zirconia frameworks were intraorally tried-in and evaluated for accuracy of fit with a silicone disclosing agent (Fit Checker, GC, Leuven, Belgium); if necessary, any pressure spot was transferred to the tooth surface and the adjustment made on the abutment tooth.

All of the frameworks were veneered by the same experienced dental technician. A conventional powder buildup veneering technique was performed by using a specifically dedicated feldspathic ceramic (Procera All Zircon, Nobel Biocare AB), whose coefficient of thermal expansion (CTE) is matched to the requirements needed for veneering the zirconia. Finally, the FDPs were glazed and polished.

Measurements of the thickness at defined points of the completed FDP were recorded, as previously described, so that the thickness of the veneering ceramic was calculated by subtraction of the framework thickness from the completed restoration thickness (Table 2).

Zirconia FDPs were intraorally tried-in again and were evaluated for accuracy of internal and marginal adaptation with a silicone disclosing agent, as previously described. Proximal and occlusal contacts were checked by means of an articulating ribbon, and occlusal adjustment was performed if needed. No treatment of the intaglio surface aimed at the cementation was performed but alcohol

Table 2 Mean thickness of veneering ceramic (mm)

Framework area	Location	Site	Mean±SD
Retainer	Mesial	Buccal	0.81±0.17
		Lingual	0.55±0.32
		Mesial	0.98±0.22
		Occlusal	0.92±0.18
	Distal	Buccal	0.79±0.25
		Lingual	0.64±0.34
		Distal	0.93±0.11
		Occlusal	0.88±0.42
Connector	Mesial	OG height	1.12±0.26
		BL width	1.37±0.29
	Distal	OG height	1.17±0.31
		BL width	1.33±0.28

OG occlusal–gingival, *BL* buccal–lingual

degreasing (80% ethanol). Before cementation, the external surfaces of the FDPs were isolated with liquid paraffin to ease cement remnant removal. The FDPs were luted by means of a resin cement (RelyX Unicem, 3M ESPE), and the cement excesses were gently removed using a plastic scaler. If necessary, occlusal adjustments were made using fine-grit diamond burs, and reshaped surfaces were meticulously polished with a ceramic polishing system (Komet nos. 9425, 9426, and 9547; Brasseler, Savannah, GA, USA).

Baseline evaluation

The baseline evaluation was performed by two experienced clinicians who did not participate in the prosthodontic procedures. The baseline evaluation was recorded 7 days after final cementation of the FDPs. A periodontal evaluation was performed assessing tooth mobility, probing pocket depth, probing attachment level, plaque control record, and bleeding on probing (BOP) at the abutment sites (test) and at the contralateral, not restored teeth (control). A pulpal vitality test using carbon was made at test and control teeth as well. Alginate impressions for study casts were taken, and occlusal relationships between the FDPs and the opposing arches were recorded.

Periapical X-rays of the abutment teeth and clinical photographs of the FDPs were taken. Moreover, the static and dynamic occlusal contacts were checked and the photographic documentation recorded.

Visual analog scales (VASs) were used to allow the patients rate the overall aesthetic and functional results of the restorations (0=worst, 10=best).

Follow-up examinations

The patients were recalled at follow-up 6 months after the baseline evaluation and then annually, for a whole observational period of 5 years. The same evaluations assessed at the baseline were repeated, and the resultant data were recorded. Proximal recurrent decays and periapical pathologies at the abutment teeth were diagnosed by means of X-rays.

The examination for technical and biologic failures or complications was made in compliance with the United States Public Health Service (USPHS) criteria, rated according to the clinical serviceability of the restorations (Table 3). The FDPs were evaluated entirely, and the worst finding was used for rating.

Statistical analysis

Descriptive statistics were applied to data using a dedicated software (SPSS 17, SPSS Inc., Chicago, IL, USA).

The Kaplan–Meier analysis was used to evaluate the 5-year survival rate of the FDPs. Every case was statistically independent, so two different curves for patients wearing one and two FDPs, respectively, were analyzed separately. A log-rank test was performed to compare the survival curves. Since only one patient was provided with a cantilevered FDP, it was excluded from the statistical analysis.

The Wilcoxon test was performed to compare the periodontal parameters of test and control teeth between the baseline and the 5-year follow-up examination, as well as the periodontal differences between test and control teeth after 5 years of clinical service. The level of significance was set at $p<0.05$.

Results

The measurements of mean thickness at the retainer and connector areas of the FDPs are shown in Table 2. All of the 37 patients and, consequently, all of the 48 three-unit zirconia FDPs were examined during 5 years of clinical function. No patient was lost at follow-up or censored.

Table 3 United States Public Health Service criteria

USPHS criteria	Alpha (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	No fracture of framework	–	–	Fracture of framework
Veneering fracture	No fracture	Chipping but polishing possible	Chipping down to the framework	New restoration is needed
Occlusal wear	No occlusal wear on restoration or on opposite teeth	Occlusal wear on restoration or on opposite teeth <2 mm	Occlusal wear on restoration or on opposite teeth >2 mm	New restoration is needed
Marginal adaptation	No probe catch	Slight probe catch but no gap	Gap with some dentin or cement exposure	New restoration is needed
Anatomical form	Ideal anatomical shape, good proximal contacts	Slightly over- or undercontoured, weak proximal contacts	Highly over- or undercontoured, open proximal contacts	New restoration is needed

As to the technical problems, neither fractures of the frameworks nor losses of retention were observed in all of the samples (Fig. 1). The cumulative survival rate was 100% while the cumulative success rate was 91.9% and 95.4% for patients wearing one and two FDPs, respectively, after 5 years according to Kaplan–Meier, considering veneering ceramic chippings as events (Fig. 2). The log-rank test performed to compare the survival curves of patients wearing one and two FDPs was not statistically significant ($p>0.05$).

During the entire observational period, three minor cohesive fractures of veneering ceramic were noticed (6.25%): the first chipping was detected, at the recall after 1 year of clinical service, on the distal connector of a maxillary premolar; after 2 years of function, two more chippings of veneering ceramic were detected by the examiners, one on the distal connector of a maxillary molar and one on the occlusal surface of a mandibular molar; the latter chipping occurred in a patient wearing two FDPs (Fig. 3). Such cohesive fractures did not impair function, neither were they noticed by the patients. Consequently, the chipped areas were carefully rounded and polished so that the FDPs remained in situ for further observation.

Eighty-two abutments (85.5%) were vital at the beginning of the study, and they all remained vital during the entire observational period. No significant differences in the average periodontal parameters between test and control teeth were detected at any follow-up examination. Neither radiographic evidence nor signs or symptoms of proximal decay or periapical pathologies were noticed during the entire follow-up period. According to the patients' VAS judgments, the overall function of the FDPs showed a mean value of 9.1 (±1.2) while the overall aesthetics scored a mean value of 9.4 (±0.4).

The technical evaluation by means of the USPHS criteria revealed very good clinical performances of the zirconia FDPs (Table 4). In terms of fracture resistance, all of the frameworks rated alpha. Regarding occlusal wear, six restorations rated bravo, and occlusal wear was detected mainly at the level of the opposing natural teeth; two of them opposed two chipped restorations.

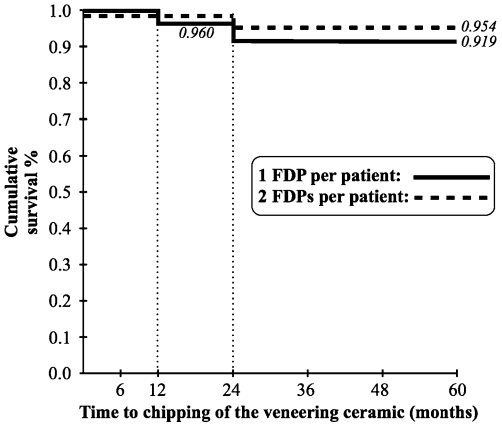

Fig. 2 Kaplan–Meier graph of chipping of the veneering ceramic in relation to time. Two different survival curves are reported for patients wearing one and two FDPs, respectively

According to the Wilcoxon test, the periodontal parameters of the test and the control teeth were not significantly different. Furthermore, the FDPs had no effect on the periodontal parameters after 5 years of clinical function (Table 5).

Discussion

Partially stabilized zirconia offers excellent flexural strength, fracture toughness, and good biocompatibility, together with acceptable marginal and internal adaptation of the restorations, all factors that undeniably contribute to the long-term success of FDPs [2].

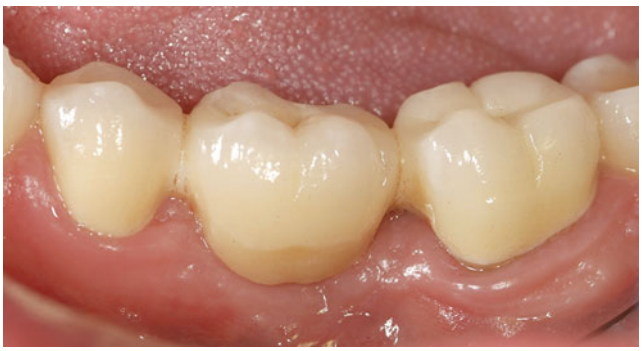

Fig. 1 Five-year recall evaluation of a zirconia FDP

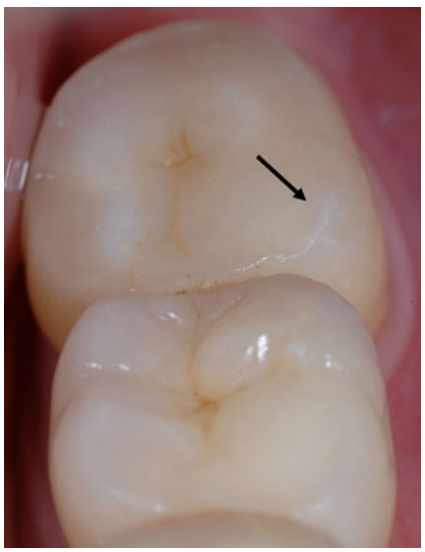

Fig. 3 Chipping (*arrow*) of veneering ceramic

Table 4 USPHS criteria scores for the FDPs

USPHS criteria	Alpha (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	48 (100%)	0	0	0
Veneering fracture	45 (93.7%)	3 (6.3%)	0	0
Occlusal wear	42 (87.5%)	6 (12.5%)	0	0
Marginal adaptation	45 (93.7%)	3 (6.3%)	0	0
Anatomical form	44 (91.7%)	4 (8.3%)	0	0

Systematic reviews of the literature reported similar survival rates between polycrystalline all-ceramic and metal-ceramic crowns. Conversely, all-ceramic FDPs showed survival rates significantly lower than metal-ceramic FDPs [4, 14, 18–31]. Failure rates of metal- and all-ceramic FDPs reported in the literature are showed in Table 6.

As for metal-ceramic, zirconia FDPs were reported to show a certain amount of both biologic complications, like secondary caries, and technical problems, such as fractures or chippings of the veneering ceramic [4, 28, 33]. Although many in vitro investigations demonstrated an efficient bond between zirconia frameworks and veneering ceramic, several clinical studies reported chipping of veneering porcelain as the most frequent technical complication [4, 8, 14, 28, 29, 32–34] (Table 7). Sailer et al. [4] reported a total chipping rate of about 33% for zirconia FDPs, whereas metal-ceramic restorations showed about 20% minor chipping after 3 years of clinical service. Many factors can be involved in such a complication. A wrong design of the framework is to be considered a risk factor for chipping, if uneven thicknesses of veneering ceramic are provided [4, 14]. Other possible variables affecting the chipping rate are the surface treatments of zirconia frameworks before the veneering procedure, the CTE mismatch between veneering ceramic and zirconia, the flexural strength of veneering ceramic, the incorporation of voids and flaws powder buildup technique, the extremely low thermal conductivity of zirconia, and the influence on furnace firing program [4, 14, 32, 34–37]. The careful attention devoted to all these aspects may explain the low chipping rate of the present investigation compared to some other clinical studies on zirconia FDPs.

Table 5 Wilcoxon test for periodontal parameters (p=0.05)

Period	Compared parameters		P value
Baseline vs 5-year recall	PPD	Mesial retainer	0.171
		Distal retainer	0.306
		Control tooth	0.488
	PAL	Mesial retainer	0.311
		Distal retainer	0.123
		Control tooth	0.184
	PCR	Mesial retainer	0.624
		Distal retainer	0.189
		Control tooth	0.251
	BOP	Mesial retainer	0.215
		Distal retainer	0.116
		Control tooth	0.089
5-year recall test vs control	PPD	Mesial retainer	0.286
		Distal retainer	0.198
	PAL	Mesial retainer	0.152
		Distal retainer	0.233
	PCR	Mesial retainer	0.293
		Distal retainer	0.182
	BOP	Mesial retainer	0.225
		Distal retainer	0.732

PPD probing pocket depth, *PAL* probing attachment level, *PCR* plaque control record

As demonstrated by some fractographic studies, chipping of the veneering ceramic is likely to originate from occlusal roughnesses [4, 14, 32]; at the same time, possible flaws or damages on the zirconia surface could induce the onset of fractures (e.g., following the adjustment of the occlusal surface, resulting in the exposure of the zirconia framework) [14]. In many studies, fractures of zirconia FDPs were often associated with insufficient connector heights [14, 32, 38, 39] leading to a reduced flexural strength. The minimum cross section for the connectors recommended by most authors is 9 mm^2 [32, 38–40]; although all of the Procera FDPs examined in the present study had been made according to such a requisite, the only technical complication detected in the present 5-year study was chipping of the veneering ceramic, particularly at the level of the connectors, due to superficial cohesive fractures. It is noticeable that one of the ceramic chippings, observed in the present investigation at the molar level of an FDP after 2 years of service, was detected in a female patient showing an evident hypertrophy of the elevator muscles (masseter, temporalis) as a family character (exhibited also by her mother and daughter). After the intraoral polishing of damaged areas, no further problems were detected.

The results of the present clinical study are in agreement with those reported in other clinical investigations, showing an efficient and predictable bond strength between zirconia

Table 6 Fixed partial dentures failure rates

Material	Reference	Percentage	Observation period
Metal ceramic	Creugers et al. 1994 [21]	8–10	10 years
	Scurria et al. 1998 [22]	<1	Per year
	Sailer et al. 2009 [4]	0	3 years
Glass ceramic	Marquardt and Strub 2006 [23]	13	5 years
	Esquivel-Upshaw et al. 2008 [24]	7	4 years
Glass-infiltrated alumina	Vult von Steyern et al. 2001 [25]	10	5 years
	Suarez et al. 2004 [26]	0	3 years
Lithia disilicate	Esquivel-Upshaw et al. 2004 [27]	7	2 years
	Esquivel-Upshaw et al. 2008 [24]	13.3	4 years
Zirconia	Sailer et al. 2007 [28]	2.2	5 years
	Molin and Karlsson. 2008 [29]	0	5 years
	Beuer et al. 2009 [14]	4.8	3 years
	Sailer et al. 2009 [4]	0	3 years
	Wolfart et al. 2009 [30]	4	4 years
	Roediger et al. 2010 [31]	6	4 years
	Tsumita et al. 2010 [2]	0	2 years

frameworks and dedicated veneering ceramic, since no adhesive failures at the interface were detected. The good mechanical characteristics of the three-unit zirconia FDPs investigated in the present study confirmed the excellent, medium-term clinical results, as previously shown in other clinical trials [4, 14, 18–31].

All of the periodontal parameters did not significantly change over the entire observational period. These results agree with those of other clinical investigations and confirm the good biological response of the soft tissues to zirconia restorations [4, 14, 18–31]. A slight gingival inflammation with positive BOP was noticed in a few cases, but no involvement of deep periodontal structures was detected until the end of the examination time.

Indubitably, a correct management of the prosthetic procedures is to be addressed as one of the main success factors in order to avoid possible biological complications like recurrent caries and periodontal problems: an accurate abutment preparation; a precise provisional prosthesis for an optimal soft tissue conditioning; a flawless impression, delayed from 10 to 14 days after tooth preparation for achieving stable and sound soft tissues; and a careful, conventional cementation are all paramount for the final results.

Table 7 Zirconia chipping rates

Reference	Percentage	Observation period
Raigrodski et al. 2006 [8]	20	31 months
Sailer et al. 2007 [28]	15.2	5 years
Tinschert et al. 2008 [34]	8	37 months
Molin et al. 2008 [29]	30	5 years

Conclusions

Within the limitations of the present study and its observational period, the excellent survival rate of three-unit posterior zirconia frameworks made with the Procera system allows to address this kind of restoration as a valid treatment option and a viable alternative to metal-ceramic FDPs in clinical cases with favorable biomechanical conditions.

The following conclusions can be drawn:

- No framework fractures were detected while minor chippings of veneering ceramic were noticed in three FDPs;
- Zirconia cores exhibited sufficient strength to ensure a predictable serviceability for three-unit posterior FDPs in the absence of excessive or parafunctional loads;
- Tooth-supported three-unit posterior zirconia FDPs showed very good mechanical performances in terms of clinical fracture resistance and marginal integrity;
- The renowned biocompatibility of zirconia was confirmed by the evidence of sound support tissues;
- The overall aesthetics and function were very satisfactory for the patients and very promising for the clinicians in the medium term.

Further randomized controlled clinical trials with longer observational periods and extended-span zirconia frameworks will be necessary to validate the long-term serviceability, the aesthetic versatility, and the biological predictability of such an innovative material.

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Conflict of interest The authors declare that they have no conflict of interest.

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